required for the extension in connection with this paper, and credit any overpayment, to Deposit Account 06-1205.

Applicants respond to the Office Action dated March 22, 2002 (Paper No. 6), in the above-identified application as follows:

REMARKS

Claims 1-17 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,047,866 to Shah or U.S. Patent No. 3,461,195 to Sebastiani. Claims 1-17 are also rejected under 35 U.S.C. §103(a) as being unpatentable over Shah or Sebastiani.

In support of this rejection, the Examiner states at pages 2-4 of the Office Action that Shah notes difficulties in tablet formulations containing lubricant and teaches a self-lubricating rotary tablet press having a lubricator to spray lubricant to the die and punch faces. The Examiner relies upon Sebastiani as teaching spraying lubricant on the punches of a tableting press using an air compressor. To the extent necessary, the Examiner further points out it would be expected Shah and Sebastiani would use a spray chamber, and that one of ordinary skill would utilize such system to provide compressed tablets which do not adhere to the punch or die during processing.

This rejection is respectfully traversed. However, prior to setting forth their bases for traversal, Applicants would like to briefly discuss the salient features of the present invention and, *inter alia*, its patentable nature over the prior art.

As recited in each of the pending claims, the present invention broadly relates to a tablet production method using punches and dies, and specifically requires use of a powdered or granulated material as a molding material. See (Claim 1 at line 3; claim 2 at line 3; claim 3 at line 3; claim 4 at line 3; claim 10 at line 4; claim 11 at line 4.)

In this regard, the present invention is not at all some tabletting method characterized by merely substituting so called "external" lubrication method for prior internal lubrication (in which tablets have been produced by mixing lubricants in powdered or granular materials prior to tabletting). Rather, the present invention provides a method which has, for the very first time, succeeded in manufacturing tablets by compressing those particular materials that have been impossible to be molded in prior art, e.g., powdered or granular materials, especially those materials which would be denaturalized or inactivated when tabletted at high pressure (see claim 1 at lines 3-5, claim 3 at lines 3-5; claim 10 at lines 4-5) as well as solid dispersions of powdered or granulated materials (see claim 2 at lines 3-4, claim 4 at lines 3-4; claim 11 at line 4). Moreover, the present invention unexpectedly provides that tabletted of powdered or granulated medicinal substances are more readily dissolved in water such that both disintegration time and absorption is improved.

The present invention is characterized by forming lubricated surface on the punches and dies used for tabletting, wherein even powdered or granular material comprising compound which is denaturalized or inactivated when tabletted at high

pressure[1/], can be compressed even when a tabletting pressure is restricted below the pressure required to practice the prior art.

Therefore, the present invention enables those of ordinary skill to utilize materials which has been impossible to be compressed and molded, thereby improving preparation technique to attribute development of disparate pharmaceutical products.

The above technical measure is not disclosed anywhere in the references cited. In particular, neither Shah or Sebastiani discloses or suggests using powdered or granular material including compound which is denaturalized or inactivated when tabletted at high pressure (claims 1, 3 and 10) or solid a dispersion (claims 2, 4 and 11) as molding material to produce a tablet. So the reference plainly does not anticipate the present invention.

Moreover, while the Examiner states Shah and Sebastiani do not disclose punches and dies located in a spray chamber, but that lubricants are applied through a spraying process so that it would be expected that a spray chamber is provided for the apparatus, such does not address the features of the claims. That is, one of the important elements of the spray chamber in the present invention is mixing lubricant with pulsating vibration air in the spray chamber.

1/ As understood by those of ordinary skill "high pressure" herein refers to the extreme tabletting pressure required for producing compressed tablets in prior art tabletting machine. This feature alone is a salient difference of the present invention from prior internal lubrication methods.

In this regard, the present inventors recognize that such is necessary so as not to scatter lubricant in atmosphere and/or not apply lubricant uniformly on the punch and die surfaces. These features are not addressed by the prior art either.

In view of the above remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-17 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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